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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/360,934      | 07/26/1999  | ANTONELLO COVACCI    | CHIR-0158           | 4878             |

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EXAMINER

BUI, PHUONG T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/18/2002

31

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/360,934**

Applicant(s)  
**Covacci et al.**

Examiner  
**Phuong Bui**

Art Unit  
**1638**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 9/17/02 and 9/20/02
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 40, 54, 58-65, 69-75, 79-86, and 90-101 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40, 54, 58-65, 69-75, 79-86, and 90-101 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 08/256,848.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>29</u> | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

1. The Office acknowledges the receipt of the Supplemental Information Disclosure Statement, Paper No. 29, filed September 17, 2002, and the Response and Amendment G, Paper No. 30, filed September 20, 2002. Claims 55-57, 66-68, 76-78 and 87-89 have been cancelled. Accordingly, claims 40, 54, 58-65, 69-75, 79-86 and 90-101 are pending and are examined in the instant application. This action is made **FINAL**.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any rejection or objection not repeated herein is hereby withdrawn.

### ***Drawings***

3. This application has been filed with informal drawings which are acceptable for examination purposes only. The Office no longer defers the filing of formal drawings.

**Accordingly, formal drawings are required in response to this Office Action.**

4. Applicant has indicated in the September 20 response that formal drawings have been submitted to the Drawing Review Branch. However, no record of submission of formal drawings is found in this application file. Applicant is required to submit formal drawings in this application in response to this Office Action.

### ***35 U.S.C. 112, second paragraph***

5. The rejection of claims 58-62, 74, 75, 79-86 and 95-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

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subject matter which applicant regards as the invention is hereby **maintained** to the extent set forth below.

In claims 55, 57-59, 76 and 78-80, Applicant's recite that the polypeptide further comprises a "derivative" of a *H. pylori* CT polypeptide. The specification recites that the cytotoxin of *H. pylori* refers to the protein whose nucleotide sequence and amino acid sequences are shown in Figures 1 and 2, "and their derivatives" (specification page 5, lines 31-34). On page 7 of the specification, Applicant describes examples of proteins having conservative amino acid substitutions. However, these examples are not specific to "derivatives". The term "derivatives" therefore has not been defined in the specification. This term renders the claims indefinite in that it is not clear how much of the protein's original structure must be retained such the resulting protein would be considered to be a "derivative".

Applicant traverses this rejection stating that, while the term "derivative" is not defined in the instant application, the specification provides guidance as to what a derivative is. This argument has not been found persuasive. The term "derivative" is a broad term covering any molecule that was somehow "derived" from a source molecule. Absent a clear limiting definition in the specification, the term has no clear metes and bounds. Though the instant specification does teach a plurality of possible alterations to a source molecule, the specification neither refers to these alterations as "derivatives", nor limits the alterations to just those

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described. Accordingly, even if the portion of the specification referred to were referencing a “derivative”, this portion fails to define what a “derivative” means.

In claims 58 and 79, it is not clear what “immunologically identifiable with” is intended to mean as this phrase has not been defined in the specification. Is the polypeptide claimed supposed to react with at least one antibody raised to an epitope of the protein of SEQ ID NO:3 or is the claimed polypeptide immunologically indistinguishable from the protein of SEQ ID NO:3?

Applicant traverses this rejection stating that the phrase “immunologically identifiable with” has been used in the specification, page 14, lines 21-30. While the specification does indeed use this phrase, the specification does not define the meaning of this phrase. As set forth above, this phrase is subject to two different interpretations. The referenced portion of the specification fails to indicate which of the two interpretations was intended.

In claims 59 and 80, it is not clear what the functional aspects are and what is intended by “which do not substantially affect”.

Applicant traverses this rejection stating that this phrase is intended to indicate that any given alteration does not substantially change the biological activity of the polypeptide. This argument has not been found persuasive because it is likewise unclear what “substantially change the biological activity of the polypeptide” means. Where the definition of a phrase is itself

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unclear, the matter of indefiniteness has not been overcome. What is the measure of a “substantial change”? What biological activity or activities are intended to be maintained?

The rejection of claim 74 is withdrawn in view of Applicant’s clarification that claim 74 recites at least an epitope of SEQ ID No:3.

***35 U.S.C. 112, first paragraph***

6. The scope of enablement rejection of claims 55, 57-59, 61, 62, 76, 78-80, 82-86, 95 and 96 are rejected 35 U.S.C. 112, first paragraph, is hereby **withdrawn** based upon Applicant’s claim amendments and response.

7. The rejection of claims 95 and 96 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is hereby **maintained** for the reasons of record. This is a written description rejection.

Applicant traverses this rejection stating that these claims recite both structural and functional properties of the polypeptide. However, these claims fail to recite sufficient structural property as required under the Office’s written description guidelines. The only structure that is required is that the polypeptide is a “recombinant polypeptide of a *Helicobacter pylori* cytotoxin”. As clearly set forth throughout the current record, there is no specific structure required by this recitation. The Office has indicated that if this phrase were limited to mean at

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least one epitope from SEQ ID No: 3 that this would both be enabling and described. However, Applicant has responded that the phrase should not be so construed and accordingly, the Office must maintain its rejection since the phrase covers a scope not possessed by Applicant.

***Claim Rejections - 35 USC § 102 and 103***

8. The rejection of claims 40, 54, 58-65, 69-75, 79-86, and 90-101 are rejected under 35 U.S.C. 102(e) as being anticipated by, or alternatively, under 35 U.S.C. 103(a), as being unpatentable over Cover et al. (U.S. Patent No. 6,054,132), is hereby **maintained** for reasons of record.

Applicant traverses this rejection for various reasons. Applicant states that Cover fails to teach any polypeptide expressed from SEQ ID No:2. Though the claims recite a polypeptide expressed from SEQ ID No: 2 and Cover fails to teach SEQ ID No: 2, Cover still anticipates or renders obvious any polypeptide expressed from SEQ ID No:2. The reason is that it is the polypeptide itself, not the nucleotide sequence encoding it that is compared to the prior art. If the encoded polypeptide is identical to that disclosed in the prior art, then the nucleotide sequence encoding the polypeptide cannot patentably distinguish that polypeptide over the prior art. The nucleotide sequence is merely a process limitation for making the polypeptide.

Applicant further traverses requesting the Office to indicate which sequences of Cover are referred to. Clearly, SEQ ID No:1 refers to a 23 amino acid sequence of the *H. pylori* cytotoxin. Applicant also asserts that the Office has failed to provide a sufficient basis for the conclusion of

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inherency regarding the non-toxicity of the polypeptide fragments of Cover. Initially, the Office noted that Cover taught the desirability of detoxifying the cytotoxin using techniques known in the art for other bacterial toxins. Moreover, the Office noted that a declaration of Del Giudice stated that identification of non-toxic fragments was routine for those skilled in the art. Thus, Cover clearly renders obvious non-toxic fragments of their cytotoxin. Notwithstanding this conclusion, the Office has asserted that the specific fragments of Cover such as the 23 amino acid fragment are inherently non-toxic. The justification for this conclusion resides in the fact that only a portion of the molecule is responsible for toxicity. While it is remotely possible that Cover unwittingly isolated fragments which included the toxic portion of the molecule, it is much more likely that these fragments did not include the toxic portion or enough of the toxic region to be toxic. Accordingly, the conclusion of inherency is founded on the high probability that Cover's fragments are non-toxic portions of the cytotoxin.

### ***Conclusion***

9. No claim is allowable.

10. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

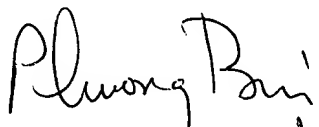
11. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui  
Patent Examiner  
Group Art Unit 1638  
December 16, 2002

  
PHUONG T. BUI  
PRIMARY EXAMINER 12/16/02